

ISO 11140-6:2022-11 (E)

Sterilization of health care products - Chemical indicators - Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	2
3	Terms and definitions	2
4	Requirements	3
4.1	General	3
4.2	Porous devices	3
4.2.1	Reference porous device (RPD)	3
4.2.2	Detector for reference porous device (RPD)	4
4.2.3	Alternative porous indicator system (APIS)	5
4.2.4	Reference porous device (RPD) response	6
4.3	Hollow devices	6
4.3.1	Reference hollow device (RHD)	6
4.3.2	Detector for reference hollow device (RHD)	7
4.3.3	Reference hollow indicator system (RHIS)	8
4.3.4	Reference hollow indicator system (RHIS) performance determination	8
4.3.5	Leakage test	9
4.4	Alternative hollow indicator system (AHIS)	9
4.4.1	General	9
4.5	Alternative hollow devices intended for multiple use	10
4.6	Test procedure for validation of conformance of the alternative hollow device to the reference hollow device (RHD)	12
5	Chemical indicator dry heat performance	13
5.1	General	13
5.2	Test 1	13
5.3	Test 2	14
6	Marking and labelling	14
6.1	Device labelling	14
6.2	Additional labelling requirements for hollow devices	14
6.3	Chemical indicators for use in hollow devices	15
Annex A (normative) Test method for performance of reference hollow indicator system (RHIS)		16
Annex B (normative) Test method for performance of alternative porous indicator system (APIS)		24
Annex C (normative) Test method for performance of alternative hollow indicator system (AHIS)		27
Annex D (informative) Relationship between chemical indicator components		28
Annex E (normative) Reference hollow device (RHD)		30
Annex F (informative) Accelerated ageing of test samples		32
Annex G (informative) Evaluation of reference hollow devices (RHDs) -- Interlaboratory results		33
Bibliography		40